

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Patent Application of
Adam J. KATZ, *et al.*

Atty. Ref.: 4094-12

Patent No. 6,777,231

TC/A.U. 1636 - Confirmation No. 9133

Issued: August 17, 2004

Examiner: William R. Dixon, Jr.

For: ADIPOSE-DERIVED STEM CELLS AND LATTICES

* * * * *

June 20, 2008

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUBMISSION OF COURT ORDER OF JUDGMENT
(WITH FINDINGS OF FACT AND CONCLUSIONS OF LAW)
AND REQUEST TO CORRECT INVENTORSHIP

On behalf of inventor Katz, the undersigned registered attorney of record hereby submits a JUDGMENT dated June 9, 2008, from the U.S. District Court, Central District of California, Western Division. Judge Marshall's related Findings of Fact and Conclusions of Law are also attached.

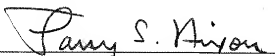
In accordance with the attached documents, it is respectfully requested that the inventorship of the above-identified issued patent be corrected to name as inventors only Messrs. Katz and Llull.

U.S. Patent No. 6,777,231
Adam J. KATZ, *et al.*

Attorney Docket No. 4094-12
SUBMISSION OF COURT ORDER

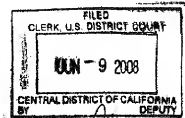
Respectfully submitted,

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNIVERSITY OF PITTSBURG OF
THE COMMONWEALTH SYSTEM
OF HIGHER EDUCATION,

Plaintiff,

v.

MARC H. HEDRICK, PROSPER
BENHAIM, HERMANN PETER
LORENZ, and MIN ZHU,

Defendants.

No. CV04-9014 CBM (AJWx)

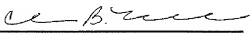
JUDGEMENT

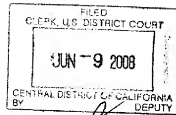
The matter before the Court, the Honorable Consuelo B. Marshall, United States District Judge presiding, is the bench trial held on Plaintiff's claim that Defendants are not proper inventors of the United States Patent No. 6,777,231. Consistent with the Findings of Fact and Conclusions of Law issued herewith, IT IS ORDERED AND ADJUDGED that judgment be entered in favor of Plaintiffs and against Defendants. The United States Patent & Trademark Office shall correct the

1 inventorship of the '231 patent to reflect that the correct inventors are Adam J. Katz
2 and Ramon Llull.

3 **IT IS SO ORDERED.**

4 DATE: June 9, 2008


5 CONSUELO B. MARSHALL
6 UNITED STATES DISTRICT JUDGE
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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNIVERSITY OF PITTSBURG OF
THE COMMONWEALTH SYSTEM
OF HIGHER EDUCATION,

Plaintiff,

v.

MARC H. HEDRICK, PROSPER
BENHAIM, HERMANN PETER
LORENZ, and MIN ZHU,

Defendants.

No. CV04-9014 CBM (AJWx)

FINDINGS OF FACT AND
CONCLUSIONS OF LAW

The matter before the Court, the Honorable Consuelo B. Marshall, United States District Judge presiding, is the bench trial held on Plaintiff's claim that Defendants are not proper inventors of the United States Patent No. 6,777,231. The Court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

JURISDICTION

The Court has jurisdiction pursuant to 28 U.S.C. § 1331 and § 1338.

FINDINGS OF FACT

- 1 1. United States Patent No. 6,777,231 ("the '231 patent'") relates to adipose-
2 derived stem cells. Joint Trial Exhibit ("JTX") 59. The claims of the '231
3 patent are:

- 4 (1) An isolated adipose derived stem cell that can differentiate into two
5 or more of the group consisting of a bone cell, a cartilage cell, a nerve
6 cell, or a muscle cell.
7 (2) An isolated, adipose-derived multipotent cell that differentiates into
8 cells of two or more mesodermal phenotypes.
9 (3) An isolated adipose-derived stem cell that differentiates into two or
10 more of the group consisting of a fat cell, a bone cell, a cartilage cell, a
11 nerve cell, or a muscle cell.
12 (4) An isolated adipose-derived stem cell that differentiates into a
13 combination of any of a fat cell, a bone cell, a cartilage cell, a nerve cell,
14 or a muscle cell.
15 (5) A substantially homogenous population of adipose-derived stem
16 cells, comprising a plurality of the stem cell of claim 1, 3 or 4.
17 (6) The adipose-derived stem cell of claim 1, 3, or 4 which can be
18 cultured for at least 15 passages without differentiating.
19 (7) The adipose-derived stem cell of claim 1, 3 or 4 which is human.
20 (8) The cell of any of claim 1, 3 or 4 which is genetically modified.
21 (9) The cell of any of claim 1, 3 or 4, which has a cell-surface bound
22 intercellular signaling moiety.
23 (10) The cell of any of claim 1, 3 or 4, which secretes a hormone.

24 JTX 59 at 18:25-51; Pre-trial Conf. Order at 2-3.

- 25 2. The '231 patent lists seven inventors. Adam J. Katz, Ramon Llull, J. William
26 Futrell, Marc H. Hedrick, Prosper Benhaim, Hermann Peter Lorenz, and Min
27 Zhu. JTX 59; Pre-trial Conf. Order at 2.
28

- 1 3. For purposes of this case, Drs. Katz, Llull, and Futrell worked only at the
2 University of Pittsburg ("UPitt"). JTX 1148. Dr. Hedrick worked at UPitt
3 from July 1997 to June 1998. He joined the University of California Los
4 Angeles ("UCLA") in July 1998. Tr. Day 3 (1) at 64:22-65:1, 75:1-77:13; Tr.
5 Day 6 (1) at 68:9-69:8. Drs. Benhaim, Lorenz, and Zhu worked only at UCLA.
6 Drs. Benhaim and Lorenz formed a lab with Dr. Hedrick at UCLA in August
7 1998, and Dr. Zhu joined this lab in June 1999. Tr. Day 6 (2) 32:25-33:18; Tr.
8 Day 7 (2) 34:7-9; Pre-trial Conf. Order at 2.
- 9 4. Drs. Katz and Llull began working at UPitt in 1993. Tr. Day 2 (1) 53:14-
10 54:11; Tr. Day 1 (1) 20:24-22:5.
- 11 5. In 1996, Dr. Katz, working with Dr. Llull, began a project in a laboratory at
12 UPitt involving the isolation, culturing, and passaging of cells from human
13 liposuctioned adipose tissue for use in fat transplantations. JTX 50; Tr. Day 2
14 (1) 60:10-76:9. Drs. Katz and Llull obtained, among other things, mature fat
15 cells ("adipocytes") and certain cells from the liposuctioned tissue's stromal
16 vascular fraction ("SVF"). Tr. Day 2 (1) 66:7-72:13, 78:22-87:12. JTX 49, 50.
- 17 6. Drs. Katz and Llull invented and obtained a patent for a device to isolate cells
18 from the SVF. JTX 100, 904. Some of Drs. Katz and Llull's isolation
19 procedures varied from those disclosed in the prior art. Tr. Day 5 (1) at 67:5-
20 68:13.
- 21 7. The Court construed "isolated" in the '231 patent to mean "in an environment
22 substantially free of other cellular or extracellular materials found in adipose
23 tissue." Feb. 13, 2007 Claim Constr. Order at 12.
- 24 8. During their research, Drs. Katz and Llull observed that under certain
25 conditions, mature adipocytes would transform into more primitive cells that
26 have a fibroblast-like appearance also known as "de-differentiation." JTX
27 50:50; Tr. Day 2 (1) at 132:12-139:10. They also observed that their de-
28 differentiated cells could, under certain conditions, "re-differentiate" or

- 1 transform back into mature adipocytes. JTX 52:27, 52:40; Tr. Day 2 (2) 4:8-
2 9:20.
- 3 9. Drs. Katz and Llull also isolated and obtained fibroblast-like cells from the
4 SVF tissue of the samples with which they worked and observed that these
5 cells could also, under certain conditions, be caused to transform into mature
6 adipocytes. The evidence demonstrates that Drs. Katz and Llull believed that
7 the cells they obtained from their isolation procedure were the same as those
8 that resulted from dedifferentiation of mature adipocytes. JTX 52:27, 52:40;
9 Tr. Day 2 (2) 4:8-11:21.
- 10 10. By late 1996, Dr. Katz had used his isolation procedure and described it in
11 terms that a scientist in the field could understand. Tr. Day 5 (1) at 57:20-58:2,
12 59:12-61:20, 63:15-65¹; JTX 50:5; JTX 51; JTX 59; JTX 100. Dr. Katz's
13 isolation procedure yields isolated adipose-derived stem cells. Tr. Day 5 (1) at
14 57:20-58:2. Dr. Katz's isolation procedure removed mature adipocytes and
15 other materials such as erythrocytes (red blood cells) found in fat tissue,
16 yielding the stem cells in an environment substantially free of other cellular or
17 extracellular materials found in adipose tissue. Tr. Day 2 (1) at 75:7-83:13,
18 JTX 50, 59. Dr. Katz also isolated adipose-derived stem cells using his
19 patented Auto-Cell Separator, which results in isolated adipose-derived stem
20 cells. Tr. Day 2 (1) 90:25-103:1; JTX 54; JTX 904. Dr. Katz's isolation
21 procedure is set forth in the '231 patent. JTX 59 at 3:9-4:6, 13:45-14:5.
- 22 11. By April 1997, Drs. Katz and Llull had the idea that their cells from adipose
23 tissue could "transdifferentiate" into multiple mesodermal lineages —
24 including bone, cartilage, fat, and muscle. They documented their results

25 ¹ On December 4, 2007, the Court found that pursuant to Federal Rule of Evidence
26 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-95
27 (1993), that Plaintiffs' expert, Dr. Farshid Guilak's, testimony will assist the trier of
28 fact to understand the evidence or determine the facts that may be in issue in the case.
The Court found that Dr. Guilak was qualified to testify as an expert on adipose-
derived stem cells.

- 1 contemporaneously by describing the above concept in laboratory notebooks,
2 letters, a January 1997 Invention Disclosure for the "Auto-Cell Separator," and
3 a February 1997 document entitled "What's So Great About Fat?" JTX 49:13,
4 49:11; JTX 43; JTX 52:41; JTX 100; JTX 535; Tr. Day 5 (1) 59:12-64; Tr. Day
5 5 (2) 42:5-11.
- 6 12. By April 1997, Dr. Katz read the literature from Dr. Arnold Caplan and
7 colleagues and drew an analogy from the cells derived from bone marrow to
8 the cells he had harvested from human liposuction tissue. Dr. Katz believed
9 that there were similarities in the ability of the cell type to differentiate into
10 many other cell types and in self-renewal. JTX 49:14-15; JTX 100 at P571;
11 JTX 401; JTX 405; JTX 1150; JTX 507; Tr. Day 5 (1) 49:17-50:6; Tr. Day 2
12 (1) at 113:5-18; Tr. Day 2 (2) 11:22-14:18, 16:15-17:3, 19:9-20:10, 20:23-
13 24:23, 17:24-18:22, 25:17-28:16, 48:15-51:24; Tr. Day 3 (1) 27:17-28:13,
14 30:1-3, 30:10-17, 86:18-23; Tr. Day 3 (2) 10:4-13:3.
- 15 13. Dr. Caplan's cells were understood to differentiate into, among other lineages,
16 bone, muscle, fat, and cartilage; they were also understood to self-renew — to
17 be capable of being passaged at least 15 times without differentiating. Tr. Day
18 5 (1) 52:4-54:6; Day 2 (1) 113:5-18; Day 2 (2) 11:22-14:18; JTX 401; JTX
19 405; JTX 1109.
- 20 14. Dr. Katz testified that Dr. Caplan's cells "looked very much like the cells I was
21 seeing with my own eyes under the microscope of cells that I had harvested
22 from human liposuction tissue." Tr. Day 2 (2) 20:23-21:9, 17:24-18:22; JTX
23 405.
- 24 15. Dr. Katz recorded his appreciation of the property of self-renewal on March 20,
25 1997. JTX 1150; JTX 1109; Tr. Day 3 (1) 24:2-25:3, 29:6-20, 86:18-23; Tr.
26 Day 2 (2) 19:9-20:10, 21:16-24:5; Tr. Day 3 (2) 10:4-13:3.
- 27 16. Self-renewal is the property of stem cells to grow and culture for extended
28 periods of time. To those skilled in the field in 1997, stem cells were thought

- 1 to self-renew for at least 15 passages in culture and there was not a single
- 2 known example of a stem cell that could not have that ability. Tr. Day 5 (1
- 3 49:17-50:6; Tr. Day 2 (1) 113:5-18; Tr. Day 2 (2) 11:22-14:18; JTX 405; JTX
- 4 1109.
- 5 17. During their research, Drs. Katz and Llull observed their cells changing shape
- 6 and form into cells with characteristics of non-adipose lineages, and, in January
- 7 1997, began testing their idea that multipotent stem cells existed in adipose
- 8 tissue, using the accepted technique of induction media experiments. JTX
- 9 52:31, 39, 47; JTX 54:44; JTX 55:7-9, 12; JTX 1147-A-1147F; JTX 55:19;
- 10 JTX 52:27, 40; JTX 50:17, 24, 27; JTX 54:45; Tr. Day 1 (1) 58:4-59:21, 64:10-
- 11 11; Tr. Day 1 (2) 8:9-9:6; Tr. Day 2 (1) 122:21-124:3, 125:25-129:22; Tr. Day
- 12 2 (2) 4:13-9:20, 11:11-21, 52:22-59:21; Tr. Day 3 (1) 6:3-8:20, 10:19-11:25,
- 13 78:16-80:22; Tr. Day 3 (2) 17:19-43:14; Day 4 (2) 59:11-60:8; 61:17-63:15,
- 14 64:14-71:7; Day 5 (1) 64:10-65:19, 60:15-61:16, 54:14-55:22.
- 15 18. The Court construed "multipotent cell" in the '231 patent to mean "a
- 16 pluripotent cell that has the capacity to differentiate in accordance with at least
- 17 two discrete developmental pathways." Feb. 13, 2007 Claim Constr. Order at
- 18 11.
- 19 19. Dr. Katz's laboratory entries on 1/20/97, 1/24/97, and 2/6/97 reflect an
- 20 induction media experiment to differentiate his cells into muscle. JTX 52:31,
- 21 39, 47; Tr. Day 2 (2) 52:22-59:21; Tr. Day 3 (1) 6:3-8:20. The induction
- 22 media used was different from that disclosed in the '231 patent. *Id.*
- 23 20. There is no reason for Drs. Katz and Llull to have conducted the induction
- 24 media experiments except to confirm or support their conceived idea that the
- 25 adipose-derived cells they had isolated were multipotent stem cells. Tr. Day 5
- 26 (1) 64:10-15; 60:15-61:20; 54:14-55:22; Tr. Day 1 (2) 61:19-62:8; Tr. Day 2
- 27 (1) 123:12-126:7. Some of Dr. Katz's experiments yielded inconclusive
- 28 results. Tr. Day 3 (1) at 11:6-9; Tr. Day 4 (1) at 26:16-20.

21. The media and protocols recorded in Dr. Katz's laboratory notebooks are known to differentiate adipose-derived stem cells into bone, muscle, fat, cartilage, and nerve cells. Tr. Day 5 (1) 63:15-25, 60:15-61:20; Tr. Day 5 (2) 14:8-17:7. Dr. Katz's laboratory notebooks would have enabled a scientist skilled in the field to isolate Dr. Katz's adipose-derived stem cells and differentiate them into each of the lineages claimed above and in the '231 patent. Tr. Day 5 (1) 57:20-61:20, 63:15-25, 60:15-61:20; Tr. Day 5 (2) 14:8-17:7.
22. In April 1997, Dr. Llull observed and documented the cells that he and Dr. Katz had isolated from fat tissue changing into cells resembling a nerve cell, a muscle cell, and a fat cell. Dr. Llull emailed a colleague regarding his idea that the adipose-derived cells could differentiate into nerve cells. Specifically, Dr. Llull stated, "[w]e are enormously intrigued by these cells ... specifically, I thought of you because we have several forms that do resemble those of a neuron ... we are eager to find out if they could behave like cytoplasmic bodies for electric stimuli ... in other words: can we document transmission of an action potential by using your electrophysiological techniques?" JTX 540; JTX 44, 44-A; Day 1 (2) 20:13-36:8, 42:20-44:19, 43:18-44:13, 39:3-41:5, 89:23. In October 1997, Dr. Katz's observed differentiation of his adipose-derived cells into nerve cells and documented his observations in his notebook and in slides. JTX 55:15, 45-47; JTX 45-A; JTX 45-B; Tr. Day 3 (1) 31:12-42:1; Tr. Day 3 (2) 55:20-57:1. In one notebook entry, there is a question mark before "nerve cell." Dr. Katz testified that the question mark means "let's do further studies ... to substantiate ..." Tr. Day 3 (1) 39:3-42:1. The exhibit shows a line running through and a line underneath "nerve cell." Dr. Katz did not cross out or otherwise reject the idea that he had observed differentiation into nerve cells. *Id.*; JTX 55:47.

- 1 23. In February 2000, Dr. Hedrick asked the University of California Office of
2 Technology Transfer to include nerve in the patent application based on a
3 “hypothesis that neuroglial differentiation may be possible.” At that point, Dr.
4 Hedrick had not conducted any nerve differentiation experiments. Tr. Day 8
5 (1) 75:15-80:23; JTX 801. July 2000 was the earliest the REBAR laboratory
6 worked on neuronal differentiation. Tr. Day 8 (1) 75:15-76:4.
- 7 24. The Court construed “substantially homogenous” in the ‘231 patent to mean
8 “consisting essentially of adipose-derived stem cells.” The term “consisting
9 essentially of” is referring to the inventive lipo-derived cells denoting that the
10 invention in claim 5 must include the lipo-derived cells and may only include
11 other non-affective materials, but it does not suggest that the substantially
12 homogenous population cells must be clonal.” Claim Const. Order at 13-14.
- 13 25. Dr. Katz used the terms “homogeneous population” and “heterogeneous
14 population” as indicators of whether all the cells in a population were the same.
15 JTX 1150; JTX 886; Tr. Day 3 (1) 85:21-86:20; Tr. Day 3 (2) 79:11-83:17; Tr.
16 Day 4 (1) 84:5-88:7.
- 17 26. The “basic and novel” property of the inventive cells is their ability to
18 differentiate into multiple lineages. Tr. Day 5 (1) 49:14-25.
- 19 27. Dr. Katz did not believe that the other cells potentially present in his stem cell
20 population materially affected his stem cells’ ability to differentiate into
21 multiple lineages. Tr. Day 3 (1) at 86:18-88:8; Tr. Day 4 (2) 82:16-83:7.
- 22 28. The other materials present in Drs. Katz and Llull’s stem cell populations did
23 not materially affect the basic and novel property of their stem cells. Tr. Day 5
24 (2) at 47:13-50:6; Tr. Day 5 (1) 49:14-25.
- 25 29. The SVF populations with which Dr. Katz worked at the University of
26 Pittsburg were the same as the PLA populations that Defendants studied at
27 UCLA. Day 7 (1) 93:19-94:4; Day 8 (1) 16:16-17:1.
- 28

- 1 30. By April 1997, Dr. Katz had the firm and definite idea that his adipose-derived
2 stem cells were human, Tr. Day 2 (2) 5:17-6:2, 20:23-21:9, 38:4-24; could be
3 genetically modified, Tr. Day 3 (1) 52:13-56:6; JTX 52:29; secreted hormones,
4 Tr. Day 3 (2) 13:4-14:21; and contain cell-surface bound intracellular signaling
5 moiety, Tr. Day 2 (1) at 103:1-106:5. These properties were known at the time
6 to scientists in the field.
- 7 31. In September 1997, Dr. Katz submitted a grant proposal entitled "Development
8 Plasticity of Cells Isolated from Human Adipose Tissue" which summarizes
9 some of the work that he and Dr. Llull had done during the previous year. JTX
10 62. The proposal describes adipose-derived progenitor cells (AdPCs), the
11 multipotent cells that Drs. Katz and Llull isolated from human fat tissue,
12 stating that "[o]ur lab has developed techniques to harvest, isolate, culture,
13 passage, dedifferentiate, differentiate, and genetically alter ... (AdPCs) in an
14 abundant and efficient manner ... and that AdPCs constitute an unimagined
15 reservoir of multipotent mesenchymal stem cells." The proposal also states
16 that "adipocytes ... transform into fibroblast-like progenitor cells which have
17 the potential to proliferate, secrete angiogenic and extracellular matrix factors."
18 *Id.*; Tr. Day 1 (2) 122:22-124:17, 128:17-130:3; Tr. Day 3 (1) 45:4-47:17; Tr.
19 Day 5 (1) 50:7-11.
- 20 32. The September 1997 proposal lists Drs. Katz and Llull, as well as non-UPitt
21 researchers Drs. Henry Young and Vincent Li as "other collaborators." The
22 proposal also lists Dr. Futrell. It does not mention Dr. Hedrick anywhere in the
23 document. JTX 62.
- 24 33. Dr. Hedrick does not appear in Dr. Katz's laboratory notebooks in connection
25 with any of the work at UPitt relevant to adipose-derived stem cells. Tr. Day 3
26 (1) 65:13-68:19; Tr. Day 4 (2) 83:89-84:14; Tr. Day 7 (1) 43:19-44:24, 51-10-
27 53:9; Tr. Day 1 (1) 49:4-14; Tr. Day 1 (2) 49:19-50:9; JTX 51-56; JTX 44;
28 JTX 540. Dr. Katz routinely documented, in his laboratory notebook, the

- 1 names of people that were involved in his work. For example, Dr. Katz
- 2 included Dr. Llull, Dr. Jeong, Dr. Bashon, Peggy Marcone, Patricia Petrosko,
- 3 Dr. CD, Oguz, and Chris Gunther in his laboratory notebooks. Day 3 (1) 8:21-
- 4 9:13, 53:21-54:13, 55:17-56:6, 56:7-57:21, 78:18-79:1; JTX 52:29, 39; JTX
- 5 53:47; JTX 55:19, 23.
- 6 34. Dr. Katz listed Drs. Hedrick and Llull as "informal scientific
- 7 supervisors/mentors" in a research agreement that required Dr. Katz to have a
- 8 mentor advisor. JTX 886; Tr. Day 4 (2) at 14:22-15:6, 43:23-44:8.
- 9 35. In late 1997 to early 1998, Dr. Hedrick wrote a research proposal that set forth
- 10 some experiments designed to characterize human adipose-derived
- 11 mesenchymal progenitor and stem cell characterization. JTX 69.
- 12 36. In April 1998, Drs. Katz, Llull, and Hedrick submitted an Invention Disclosure
- 13 to UPitt entitled "Adipose (fat)-derived Multipotent Precursor Cells and Uses
- 14 Thereof." JTX 46. The Invention Disclosure states that isolated stromal cells
- 15 from human fat tissue "can be induced to develop into fat, bone, cartilage, and
- 16 muscle tissues given the appropriate culture milieu based on our research
- 17 results." *Id.* The Invention Disclosure lists October 1996 as the first date of
- 18 conception. *Id.* at P1319.
- 19 37. The Regenerative Bioengineering and Research ("REBAR") Lab was founded
- 20 at UCLA in August 1998 by Drs. Benhaim, Lorenz, and Hedrick. JTX 9; JTX
- 21 1; JTX 64; JTX 83; Tr. Day 8 (1) at 7:5-8; Tr. Day 8 (2) at 24:2-5. Dr.
- 22 Hedrick continued to research "the further delineation of the multipotent nature
- 23 of human lipo-derived cells." JTX 165.
- 24 38. Some time in 1998, Dr. Katz focused his researched efforts more on "the
- 25 exploitable potential of liposuctioned fat tissue for transplantation, tissue
- 26 engineering, and gene therapy applications." *Id.*
- 27 39. In March 1999, UPitt filed Provisional Patent Application No. 60/123,711.
- 28 Pre-trial Conf. Order at 3. The application claims a method of "differentiating

- 1 adipose-derived stem cells” by “isolating and expanding” cells and then
- 2 culturing them in media to induce osteogenic (bone), adipogenic (fat),
- 3 chondrogenic (cartilage), and myogenic (muscle) differentiation. JTX 302.
- 4 This application lists Drs. Katz, Lull, Futrell, and Hedrick as inventors. The
- 5 ‘231 patent claims priority over to the Provisional Patent Application No.
- 6 60/123,711 under 35 U.S.C. § 119(e). JTX 59.
- 7 40. In June 1999, Dr. Zhu joined the REBAR lab. JTX 68; Pre-trial Conf. Order at
- 8 3. In late 1999, the UCLA researchers differentiated SVF cells using a variety
- 9 of media. Tr. Day 6 (1) at 9:8-21. They also identified telomerase enzyme, a
- 10 stem cell marker, in a heterogeneous population of SVF cells. *Id.* at 9:22-25;
- 11 JTX 870.
- 12 41. In October 1999, UPitt filed Provisional Patent Application No. 60/162,462
- 13 (“the Second Provisional”), listing Drs. Katz, Lull, Futrell, and Hedrick as
- 14 inventors. JTX 303; Pre-trial Conf. Order at 3. The Second Provisional
- 15 acknowledged that cloning experiments were ongoing to determine whether
- 16 adipose-derived stem cells exists in human liposuctioned fat tissue and the
- 17 similarities of adipose-derived stem cells to bone marrow-derived
- 18 mesenchymal stem cells. JTX 303 at 41.
- 19 42. Research at UCLA showed that adipose-derived stem cells are distinct from
- 20 prior art bone marrow-derived stem cells because they respond differently to
- 21 induction media. JTX 804; Tr. Day 7 (1) 16:6-17:22.
- 22 43. In late 1999 and early 2000, Defendants were able to clone single adipose-
- 23 derived cells. JTX 863; JTX 864; JTX 873-875; Tr. Day 7 (2) at 14:6-16:17,
- 24 21:21-33:19; *see also* JTX 812, JTX 813.
- 25 44. In February 2000, Dr. Hedrick submitted an Invention Disclosure to UCLA for
- 26 stem cells derived from adipose tissue. JTX 105. He wrote “1997” as the date
- 27 the invention was “first conceived” and “first successfully tested” and indicated
- 28 that the work underlying the disclosure began in 1996. JTX 105; Tr. Day 7 (1)

78:15-81:7. Also in early 2000, Dr. Hedrick began providing UPitt's patent attorney with information to include in the '231 patent including recipes for the induction medium reported in the examples section of the '231 patent. JTX 801.

45. On March 10, 2000, UPitt filed International Patent Application PCT/US00/06232. JTX 59. This application lists all seven of the named inventors of the '231 patent. *Id.*

46. On October 29, 2004, UPitt filed the current action to remove Defendants as inventors of the '231 patent. On February 9, 2006, Defendants filed a counterclaim against Plaintiffs to remove Drs. Katz, Llull, and Futrell as inventors of the patent. Dr. Futrell filed an unopposed motion to dismiss himself from the case which the Court granted on June 20, 2006. On February 13, 2007, the Court issued an Order construing disputed claims in the patent. On August 9, 2007, the Court granted Plaintiffs' motion for summary judgment finding that Drs. Katz and Llull are properly named inventors; however, the Court denied summary judgment for Plaintiffs that Drs. Benhaim, Lorenz, and Zhu are not proper inventors of the '231 patent, stating material issues of fact in dispute regarding whether Plaintiffs alone conceived of the invention. The Court also denied Defendants' motion for summary judgment in its entirety. 8/9/07 Order at 3, 17-18.

CONCLUSIONS OF LAW

47. There is a presumption that an individual named as inventor of a patent is correctly named as an inventor of a patent. *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997). Removal of a named inventor from a patent requires proof by clear and convincing evidence. *Cook Biotech. Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006); *Eli Lilly and Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358-59 (Fed. Cir. 2004). Plaintiffs must show

- 1 that they conceived of every claim of the patent and that any contribution by
2 defendants to the conception of each and every claim was insignificant. *Id.*
- 3 48. "A joint invention is the product of a collaboration between two or more
4 persons working together to solve the problem addressed ... [p]eople may be
5 joint inventors even though they do not physically work on the invention
6 together or at the same time, and even though each does not make the same
7 type or amount of contribution, ... [t]he statute does not set forth the minimum
8 quality or quantity of contribution required for joint inventorship." *Burroughs*
9 *Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994) (internal
10 citations omitted). However, to be a joint inventor, an individual must make a
11 contribution to the conception of the claimed invention that is not insignificant
12 in quality, when the contribution is measured against the dimension of the full
13 invention. *Cook*, 460 F.3d at 1373; *see Eli Lilly*, 376 F.3d 1352, 1358-59 (Fed.
14 Cir. 2004).
- 15 49. "Conception is the touchstone of inventorship, the completion of a mental part
16 of invention." *Burroughs*, 40 F.3d at 1228. It is "the formation in the mind of
17 the inventor of a definite and permanent idea of the complete and operative
18 invention." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367,
19 1376 (Fed. Cir. 1986). Conception is complete when "the idea is so clearly
20 defined in the inventor's mind that only ordinary skill would be necessary to
21 reduce the invention to practice, without extensive research or
22 experimentation." *Burroughs*, 40 F.3d at 1228. The obviousness of a claimed
23 feature is irrelevant to the conception determination. *Id.* at 1232.
- 24 50. "A party must show possession of every feature recited in the count, and that
25 every limitation of the count must have been known to the inventor at the time
26 of the alleged conception." *Hitzeman v. Rutter*, 243 F.3d 1345, 1354 (Fed. Cir.
27 2001) (internal citations omitted).
- 28

- 1 51. Conception occurs on “the date the inventor first appreciated the fact of what
2 he made.” *Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341
3 (Fed. Cir. 2001). The inventor need not be the first to appreciate the
4 patentability of the invention. *Id.*
- 5 52. Conception requires an inventor to be able to define the invention with
6 particularity so as to distinguish it from prior art. *Amgen, Inc. v. Chugai*
7 *Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). However, the inventor
8 need not use the exact same wording that later appears in the issued patent
9 claims. *Mycogen Plant Sci. Inc. v. Monsanto Co.*, 243 F.3d 1316, 1336 (Fed.
10 Cir. 2001).
- 11 53. “Conception is a prerequisite to an adequate written description” because
12 “[o]ne cannot describe what one has not conceived.” *Falkner v. Inglis*, 448
13 F.3d 1357, 1367, n.13 (Fed. Cir. 2006).
- 14 54. An inventor may conceive of an invention without establishing whether the
15 invention would work for its intended purpose. *See Burroughs*, 40 F.3d at
16 1231; *Board of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys.*
17 *Inc.*, 487 F.Supp. 2d 1099, 1116-17 (N.D. Cal. 2007).
- 18 55. Research that occurs after conception, including research that confirms the
19 operability of an invention or “simply reduces the inventor’s idea to practice”
20 does not support joint inventorship. *Ethicon, Inc. v. United States Surgical*
21 *Corp.*, 135 F.3d 1456, 1460 (Fed.Cir.1998).
- 22 56. Contributions relating to aspects of the invention that do not find their way into
23 the defined invention in a patent claim cannot serve as the basis for a claim of
24 co-inventorship. *See Eli Lilly*, 376 F.3d at 1362 (citing *Ethicon*, 135 F.3d at
25 1461-63 for “granting co-inventorship status provided the person ‘contributed
26 to the invention defined by’ a claim or ‘if [the person’s] contribution found its
27 way into the defined invention’ in a claim.”)

28

- 1 57. Conception does not require conclusive physical experiments, scientific proof,
2 and confirmation of operability of the concept or idea in the inventors' minds.
3 *Burroughs*, 40 F.3d at 1227-28, 1230; *In re Jolley*, 308 F.3d 1317, 1321 (Fed.
4 Cir. 2002). A suggestion to "evaluate" a "possibility" can be enough to
5 demonstration conception, and no rule 'excludes "research proposals" as
6 evidence of conception.' *In re Jolley*, 308 F.3d at 1321, 1323. However if
7 experimentation reveals uncertainty that so undermines the specificity of the
8 inventor's idea, then conception is not complete. *See Burroughs*, 40 F.3d at
9 1229.
- 10 58. While reduction to practice is not required for conception, it ordinarily
11 provides "the best evidence that an invention is complete." *Pfaff v. Wells*
12 *Elecs., Inc.*, 525 U.S. 55, 66 (1998); *see Trovan Ltd. v. Sokymat Sa.*, 299 F.3d
13 1292, 1309 (Fed. Cir. 2002) ("Gustafson's reduction to practice alone is
14 evidence that Gustafson had a definite and permanent idea of the complete and
15 operative invention.").
- 16 59. Conception is a mental act, so "courts require corroborating evidence of a
17 contemporaneous disclosure that would enable one skilled in the art to make
18 the invention." *Burroughs*, 40 F.3d at 1228.
- 19 60. A court may infer conception of a claim limitation from the fact that artisans in
20 the field would have understood the invention that had been conceived to
21 possess the limitation, even in the absence of contemporaneous documentation
22 expressly reciting the limitations. *Burroughs*, 40 F.3d at 1231-32.
- 23 61. The purpose of the corroboration requirement is to determine if an inventor's
24 testimony related to actual research or whether it constitutes "litigation-
25 inspired fabrication." *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264
26 F.3d 1344, 1350-51 (Fed. Cir. 2001). "Because documentary or physical
27 evidence is created at the time of conception, ... the risk of litigation-inspired
28 fabrication or exaggeration is eliminated." *Id.* at 1351; *Mahurkar v. C.R. Bard*,

- 1 *Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). “All of the evidence ... must be
- 2 considered as a whole.” Conception of the entire invention need not be
- 3 reflected in a single document. *Price v. Symsek*, 988 F.2d 1188, 1196 (Fed.
- 4 Cir. 1993).
- 5 62. An alleged co-inventor’s testimony, or the testimony of the inventor himself,
- 6 standing alone, cannot provide clear and convincing evidence of conception.
- 7 *Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004);
- 8 *see Ethicon*, 135 F.3d at 1461. “Independent corroboration may consist of
- 9 testimony of a witness ... to the actual reduction to practice or it may consist of
- 10 evidence of surrounding facts and circumstances independent of information
- 11 received from the inventor.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157,
- 12 1171 (Fed. Cir. 2006). Corroboration is not required for physical exhibits as a
- 13 condition for its serving as evidence of conception. *See Mahurkar*, 79 F.3d at
- 14 1577-78 (the court does not require corroboration since the trier of fact can
- 15 conclude for itself what documents show, aided by testimony as to what the
- 16 exhibit would mean to one skilled in the art.)
- 17 63. “Documentary or physical evidence that is made contemporaneously with the
- 18 inventive process provides the most reliable proof that the inventor’s testimony
- 19 has been corroborated.” *Sandt*, 264 F.3d at 1350-51.
- 20 64. The court applies a “rule of reason” analysis to determine whether the
- 21 inventor’s prior conception testimony has been corroborated; it looks at all
- 22 pertinent evidence so that a sound determination of the credibility of the
- 23 inventor’s story may be reached. *See Price*, 988 F.3d at 1195; *Medichem*, 437
- 24 F.3d at 1170. “Under the ‘rule of reason’ standard for corroborating evidence,
- 25 the trial court must consider corroborating evidence in context, making
- 26 necessary credibility determinations, and assign appropriate probative weight
- 27 to the evidence to determine whether clear and convincing evidence supports a
- 28

- 1 claim of co-inventorship.” *Ethicon*, 135 F.3d at 1464 (internal citations
2 omitted).
- 3 65. By April 1997, Drs. Katz and Llull had the definite and permanent idea,
4 supported by corroborated evidence documented contemporaneously or in
5 subsequent writings that the cells they had isolated from human adipose tissue
6 were capable of differentiating into fat, muscle, bone and cartilage cells or
7 multiple mesodermal lineages. *See Findings of Fact* ¶¶ 11-14, 17- 21, 31; *see*
8 *also Sandt*, 264 F.3d at 1350-51.
- 9 66. The media and protocols in Dr. Katz’s notebooks would enable one skilled in
10 the field to isolate adipose-derived stem cells and differentiate them into each
11 lineage claimed in the ‘231 patent. *See Findings of Fact* ¶ 21; *see Sandt*, 264
12 F.3d at 1350-51; *Burroughs*, 40 F.3d at 1223, 1228.
- 13 67. Also, by April 1997, Drs. Katz and Llull had the definite and permanent idea
14 that the above noted cells could be passaged fifteen times without
15 differentiating. The Court infers conception of this claim limitation from the
16 fact that artisans in the field would have understood the possession of this
17 limitation even in the absence of contemporaneous documentation expressly
18 reciting the limitation by number. *See Burroughs*, 40 F.3d at 1231-32; *see*
19 *Findings of Fact* ¶¶ 13, 15, 16.
- 20 68. In April and October 1997 respectively, Drs. Llull and Katz had the definite
21 and permanent idea, supported by corroborated evidence, that the cells they
22 had isolated from human adipose tissue were capable of differentiating into
23 nerve cells. *See Findings of Fact* ¶¶ 21, 22. While Drs. Katz and Llull both
24 expressed a need to explore this possibility further, the Court finds the
25 evidence sufficient to demonstrate conception. *See In re Jolley*, 308 F.3d at
26 1321, 1323. Dr. Hedrick’s exploration of differentiation into nerve cells
27 occurred after Drs. Katz and Llull’s conception. *See Findings of Fact* ¶ 23; *see*
28 *also Ethicon*, 135 F.3d at 1460.

69. 35 USC Section 102 (g)(2) provides that “[a] person shall be entitled to a patent unless ... before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.” 35 U.S.C. § 102 (g)(2). Section 102 (g) pertains to “an interference” where the court must determine “priority of invention.” *See id.* The current case involves a suit to correct misjoinder of a named inventor under 35 U.S.C. Section 256 and not “interference” to determine priority of invention. In addition, Defendants did not preserve the issue of abandonment for trial. *See Pre-trial Conf. Order.*
70. Additionally, before Dr. Hedrick’s arrival at UPitt, Drs. Katz and Llull had the firm and definite idea that their cells could be cultured in substantially homogeneous populations. *See Findings of Fact ¶¶ 24-29, 31.*
71. Drs. Katz and Llull had the firm and definite idea that the adipose-derived stem cells were human, could be genetically modified, secreted hormones, and contained cell-surface bound intracellular signaling moiety by April 1997. *See Findings of Fact ¶ 30.* Artisans in the field would have understood possession of this limitation even in the absence of contemporaneous documentation expressly reciting the limitations. *See Burroughs*, 40 F.3d at 1231-32.
72. Drs. Katz and Llull defined their invention with particularity so as to distinguish it from prior art; their ideas were supported by corroborated evidence, considered as a whole. *See Findings of Fact ¶¶ 5, 6, 8-17, 19-22, 27, 28, 31; see Amgen, Inc.*, 927 F.2d at 1206; *see also Price*, 988 F.2d at 1195. At times, Dr. Katz did not use the exact same wording that later appears in the patent language; however, this is not required for conception. *See Mycogen*, 243 F.3d at 1336. It is also immaterial whether they appreciated the legal patentability or novelty of their invention. *See Dow*, 267 F.3d at 1341.
73. Defendants’ research after conception confirmed the operability of the invention and included recipes for the induction medium reported in the

1 examples section of the '231 patent. *See* Findings of Fact ¶¶ 40, 42-44. This,
2 however, does not support a claim of co-inventorship since the contributions
3 occurred after conception. *See Ethicon*, 135 F.3d at 1460. Also, the examples
4 listed are not specifically noted in the patent claims. *See Eli Lilly*, 376 F.3d at
5 1362 (internal citation omitted).

6 74. Clear and convincing evidence demonstrates that Drs. Katz and Llull
7 completed conception of all of the claims of the '231 patent at UPitt prior to
8 Dr. Hedrick's arrival at UPitt and/or prior to any of the Defendants' work at
9 UCLA. *See* Findings of Fact ¶¶ 5-6, 8-22, 24-28, 30-32.

10 75. Dr. Hedrick did not contribute to the conception of any of the claims of the
11 '231 patent. The remaining defendants did not contribute to the conception of
12 any of the claims of the '231 patent. *See* Findings of Fact ¶¶ 23, 40, 42-44, 56.

13 76. Clear and convincing evidence demonstrates that Drs. Katz and Llull are the
14 sole inventors of the claims of the '231 patent.

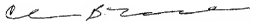
15 CONCLUSION

16 The Court finds that Drs. Katz and Llull are the sole inventors of the '231
17 patent and that Drs. Hedrick, Benhaim, Lorenz, and Zhu are not inventors.
18 Accordingly, pursuant to 25 U.S.C. § 256, the U.S. Patent & Trademark Office shall
19 correct the inventorship of the '231 patent to reflect that the correct inventors are
20 Adam J. Katz and Ramon Llull.

21 To the extent that any findings of fact constitute conclusions of law, they are
22 adopted as such, and to the extent that the conclusions of law constitute findings of
23 fact, they are adopted as such.
24

25 **IT IS SO ORDERED.**
26

27 DATE: June 9, 2008

28 
CONSUELO B. MARSHALL
UNITED STATES DISTRICT JUDGE